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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,468	03/15/2001	Michael Wholey	180431-00015	5503

29694 7590 05/15/2006

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,468

Applicant(s)

WHOLEY ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8-11 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/15/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 12-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 March 2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,406,786 to Hein.

In the specification and figures, Hein discloses the apparatus as claimed by applicant. In particular, Hein discloses a filter device with an elongated chamber (1, 3, 6), a paddle assembly 5 disposed within the chamber, a porous floor 8 disposed within and extending across the chamber, and means for coupling (2, 7) the filter device to an artery and a vein (see columns 3-4, FIG 2).

With regard to applicant's "means for coupling" of claim 1, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for applicant's definition.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." (MPEP § 2181).

Applicant's specification discloses that tubes 21 and 33 connect to the filter and, in turn, are connectable to patient blood vessels. Hein discloses that the ends of his filter device comprise tubes 2, 7, which perform the same function as the claimed "means for coupling," since both structures channel fluid from a source through the filter and back out. Therefore, examiner considers Hein's tubes 2, 7, to be the functional equivalent of applicant's "means for coupling," meeting the limitations of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein (see rejection above) in view of US 4,399,042 to Stannard et al.

In the specification and figures, Hein discloses the apparatus as claimed with the exception of porous paddles. With regard to claims 2 and 3, Stannard discloses a filter apparatus with a porous filter bed 26 and paddles or blades 44 that agitate the fluid in the filter chamber and scrape the particulate material from the filter bed (see column 4, FIGS 4-5). The blades are mounted on and rotate about a vertical shaft 42 that supports the blades (see column 5, lines 40-45), and may comprise a porous structure that allows water or fluid to pass through them while retaining the solids in the filtered fluid (see column 6, lines 26-38). With regard to applicant's recitation of "micro pores," examiner has interpreted the limitation (absent any specific allusion to size in the specification) to mean small pores that allow only fluid to pass through, while retaining clots. ("Micro" is broadly interpreted by the examiner to merely mean "very small." See Merriam Webster's Collegiate Dictionary, 10th Ed, 2001.) Stannard specifically discloses that the porosity of the blades are selected to allow fluid to pass, but not particulate matter. Since the Stannard device functions in the same manner as claimed by applicant, and applicant fails to disclose the size of the claimed "micro pores," the combined Hein and Stannard disclosures meet the limitation of the claim. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the agitating means or paddles disclosed by Hein with porous surfaces and a rotator shaft as disclosed by Stannard in order to allow water to pass

through the blades and give the blades extra stability when passing through accumulated particulate matter, as taught by Stannard.

With regard to claim 4, Hein discloses a cylindrical chamber with a proximal end 1 and a distal end 6, wherein the filter bed 4 is disposed at distal end 6 (see FIG 1).

With regard to claim 5, Stannard specifically discloses that the filter bed may filter particulate matter from a fluid flowing past the filter. Since the filter disclosed by Hein and Stannard is capable of performing the filtering function claimed by applicant, it meets the limitations of the claim.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein in view of US 4,399,042 to Stannard et al, as applied above, further in view of US 6,059,745 to Gelbfish.

In the specification and figures, Hein and Stannard disclose the apparatus as claimed by applicant with the exception of one-way valves at the inlet and outlet of the filter device. Gelbfish discloses a thrombectomy apparatus with an anterior inlet end (generally at 18) and a distal outlet end (generally at 14) and a filter chamber 21 with a porous filter 20 disposed in the chamber to trap blood clots. The device comprises one way-valves 30 and 32 in the anterior and distal ends of the device in order to prevent backflow of trapped clots to the patient (see column 6, lines 35-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the one-way valves disclosed by Gelbfish to the filtration apparatus disclosed by Hein and Stannard in order to prevent backflow of debris to the patient, as taught by Gelbfish.

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7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein in view of US 4,399,042 to Stannard et al, in view of US 6,059,745 to Gelbfish, as applied above, further in view of US 6,416,665 to McGrath.

In the specification and figures, Hein, Stannard, and Gelbfish disclose the device as claimed with the exception of a motor or engine that drives the shaft. Stannard specifically discloses that the device may comprise drive motor 218, but does not disclose that it comprises a separate shaft that is coupled to blade shaft 42. McGrath discloses a filtration apparatus wherein a filtration membrane 4 is mounted on axis 5 and rotated about chamber 3. The axis 5 is coupled by a pulley 8 to a shaft (unlabeled) that is driven by motor 9 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the motor and drive system disclosed by McGrath to the filtration system disclosed by Hein, Stannard, and Gelbfish in order to provide rotational motion to the axis and filtration membrane, as taught by McGrath.

Allowable Subject Matter

8. Claims 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the invention claimed by applicant. In particular, the prior art fails to disclose a filter with a cylindrical housing, a porous floor,

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porous paddles, valves, drive motor and shaft as claimed, and coupling structure as claimed, along with the other steps and limitations of the claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

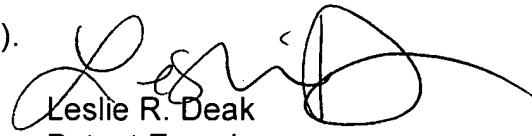
- a. US 6,645,221 Richter
 - i. Thrombectomy apparatus with paddles
- b. US 4,755,300 Fischel et al
 - ii. Couette membrane filtration apparatus

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
4 May 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

